09-14-06

SEP 1 3 2006

PTO/SB/21 (07-06)
Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

AF

TRANSMITTAL FORM (to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Alexandria, VA 22313-1450 on the date shown below.

Richard W. Warner

Typed or printed name

Signature

Application Number 10/614,550

Filing Date July 7, 2003

First Named Inventor Robert G. Metzger

Art Unit 3738

Examiner Name Christopher D. Prone

Attorney Docket Number 5490-000209/CPA

ENCLOSURES (check all that apply)								
Fee Transmittal Form		☐ Drawing(s)		After Allowance Communication to Technology Center (TC)				
Fee Attached		Licensing-related Papers		Appeal Communication to Board of Appeals and Interferences				
Amendment / Reply		Petition		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)				
After Final		Petition to Convert to a Provisional Application		Proprietary Information				
Affidavits/declaration(s)		Power of Attorney, Revocation Change of Correspondence Address		Status Letter				
Extension of Time Request		Terminal Disclaimer		Other Enclosure(s) (please identify below):				
Express Abandonment Request		Request for Refund CD, Number of CD(s)			Pre-Appeal Brief Request for Review with 5-supplemental pages attached; return postcard			
☐ Information Disclosure Statement								
Certified Copy of Priority Document(s)		Remarks The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed.						
Response to Missing Parts/ Incomplete Application		Account No. 00-0750. A duplicate copy of this sheet is enclosed.						
Response to Missing Parts under 37 CFR 1.52 or 1.53								
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT								
Firm or Individual name Harness, Dickey &		Pierce, P.L.C.	Attorney Name Richard W. Warner		Reg. No. 38,043			
Signature	That is way							
Date	September 13, 2006							

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450,

Express Mail Label No. EL 623312039 US

September 13, 2006



☐ *Total of

forms are submitted.

Docket Number (Optional)

PTO/SB/33 (07-06)

Approved for use through xx/xx/200x. OMB 0651-00xx

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays an OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVI	EW	5490-000209/CPA		
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]	Application Number 10/614,550 First Named Inventor		Filed July 7, 2003	
	Robert G. Met	zger		
On <u>9-13-06</u> Signature	Art Unit 3738		Examiner Christopher D. Prone	
(
Typed or printed name <u>Carol Naumann</u>				
Applicant requests review of the final rejection in the above-in filed with this request.	dentified appl	ication. No amo	endments are being	
This request is being filed with a notice of appeal.				
The review is requested for the reason(s) stated on the attack Note: No more than five (5) pages may be provided.	ned sheet(s).			
I am the	,			
☐ applicant/inventor	The / w	, Was		
assignee of record of the entire interest.		Signature		
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	·	Richard W. Warne		
☑ attorney or agent of record. Registration number 38,043.		248-641-1600 Telephone numbe		
attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34		September 13, 200		
NOTE: Signatures of all the inventors or assignees of record of the entire int forms if more than one signature is required, see below*.	erest or their rep		equired. Submit multiple	



Application No.:

10/614,550

Filing Date:

July 7, 2003

Applicant:

Robert G. Metzger

Group Art Unit:

3738

Examiner:

Christopher D. Prone

Title:

ELONGATED FEMORAL COMPONENT

Attorney Docket:

5490-000209/CPA

Mail Stop AF

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

REMARKS/ARGUMENTS INCLUDED WITH A PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants respectfully submit that there are clear errors in the rejection set forth in the Office Action mailed June 13, 2006. Specifically, the cited art fails to disclose each and every feature of the claims. As a result, the Office Action fails to set forth a prima facie rejection of the pending claims. Therefore, this Pre-Appeal Brief Request For Review is necessary and proper.

The Pending Claims

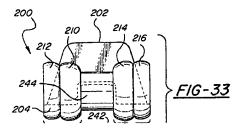
All pending claims stand rejected under 35 U.S.C. § 102(b) in light of Pottenger et al. (U.S. Patent No. 6,039,764). Independent Claims 1, 10, 18, and 24 each recite, in part, "a knee joint prosthesis system." This **system** comprises "a first femoral component" and a "second femoral component" **each** having different maximum medial to lateral dimensions. The first and second femoral components, as defined by the independent claims and disclosed in the specification, are two separate and distinct femoral components. The Final Office Action's citation to Pottenger et al, which discloses a single femoral component having two different condyle regions, as anticipating the claimed "first femoral component" and "second femoral component" is **clear error**.

Remarks and Arguments

The Final Office Action, mailed June 13, 2006, rejected all of the pending claims under Section 102 based on Pottenger et al. The Final Office Action based its rejection on the following:

Pottenger discloses the invention substantially as claimed being modular knee joint system comprising <u>first and second femoral components</u> (214) and (216)....

6-13-06 Office Action at 2. The relevant portion of Figure 33 from Pottenger et al. that the 6-13-06 Office Action is referring to is provided below.



Thus, the Final Office Action asserts that the elements at reference numerals 214 and 216 of the Pottenger et al. reference, which are different portions of a condyle portion of a <u>single</u> femoral component, anticipate the claimed system comprising a "first femoral component" and a "second femoral component."

The Final Office Action, for the first time and contrary to the 12-27-05 Non-Final Office Action, asserts that the claimed "first femoral component" and the "second femoral component" are anticipated by two different portions of a single femoral component. **This is clear error.**

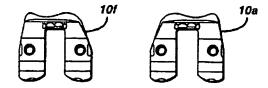
The claimed "first femoral component" and "second femoral component" refer to two separate and distinct femoral components, one of which can be selected by a surgeon for implantation in a patient. The claimed "first femoral component" and "second femoral component" are **not** two areas of a single femoral component as disclosed by Pottenger et al.

12-27-05 Non-Final Office Action

In the 12-27-05 Non-Final Office Action the Examiner acknowledged that the claimed "first femoral component" and the "second femoral component" indeed refer to two separate and distinct femoral components. In the Non-Final Action the Examiner rejected the pending claims under Section 103 in light of Colleran et al. (U.S. Patent No. 5,776,201). The Non-Final Action based its rejection on the following:

Colleran discloses the invention substantially as claimed being modular knee joint system comprising first and second femoral components (10a) and (10f)...

12-27-05 Office Action at 2 (emphasis added). The relevant portion of Figure 4 of Colleran et al. that the Office Action is referring to is provided below.



Thus, the 12-27-05 Office Action acknowledged that the claimed "first femoral component" and "second femoral component" are separate and distinct femoral components by comparing the two claimed femoral components to the components illustrated in Colleran at 10a and 10f. Therefore, the Non-Final Office Action also shows that the Examiner considered the "first femoral component" and the "second femoral component" to be separate and distinct when searching the invention.

The Specification

The specification supports no other conclusion than that the claimed system comprising a "first femoral component" and a "second femoral component" are separate and distinct femoral components. For example, paragraph [0043] recites that <u>each</u> femoral component includes "a first condylar portion 38 and a second condylar portion 40 that provides a first femoral bearing surface 42 and a second femoral bearing surface 44, respectively." These are features of a typical femoral component operable to be implanted in a patient.

Further, paragraph [0066] recites, with reference to Figures 10 and 11 for exemplary purposes only, "The present invention gives a surgeon the ability to choose a femoral component for a knee joint prosthesis from a variety of different femoral components, such as the CR femoral 32a and 32b, that have a varying M/L dimension and a constant anterior/posterior dimension allowing constant femoral engagement."

As set forth in the specification and as illustrated in the figures, the first femoral component and the second femoral component are two separate components, one of which can be selected by a surgeon for implantation. Therefore, the Final Office Action's rejection of the claims based on the single femoral component of the Pottenger reference is clear error.

The Dependent Claims

The fact that the first and second femoral components are two distinct femoral components that can be selected by a physician for implantation in a patient is also set forth in the dependent claims which, through the doctrine of claim differentiation, further define the independent claims.

For example, dependent Claim 6, recites, "wherein said first femoral component is a first cruciate femoral component and said second femoral component is a second posterior stabilized (PS) femoral component." Claim 7 recites, "wherein said first femoral component is a first cruciate femoral component and said second femoral component is a second fully constrained femoral component."

As set forth in the specification, cruciate femoral components, posterior stabilized (PS) femoral components, and fully constrained femoral components are each separate and distinct types of femoral components that accommodate the needs of different patients. For example, a fully constrained femoral component is used when a patient has severe soft tissue damage or loss and a posterior stabilized (PS) femoral component is used when the patient has an intermediate level of soft tissue damage, as is known in the art. If both the first femoral component and the second femoral component is a single femoral component, as the Examiner asserts, then the single femoral component would also have to be both a fully constrained femoral component and a PS femoral component, which is not possible as is known in the art.

A single femoral component cannot be more than one of a cruciate femoral component and a PS femoral component, or a fully constrained femoral component. Paragraphs 39, 43, 53, and 57 and Figure 2 describe and illustrate some of the differences between these different femoral components. Even if these different femoral components are interpreted broadly, as the June 13, 2006 Office Action indicates, a single femoral component again cannot be both a cruciate femoral component and a posterior stabilized femoral component or a fully constrained femoral component.

Dependent Claims 3 and 13 recite "a tibial component." Use of the term "component" in Claims 3

and 13 again refers to a separate and distinct component from the first and second femoral components of

the independent claims. The Final Office Action acknowledges this fact by comparing the claimed tibial

component to the separate tibial component at reference numeral 230 of Pottenger et al. Thus, the Office

Action's interpretation of "component" with respect to the independent claims is inconsistent with the

interpretation of the dependent claims reciting a "tibial component."

Conclusion

As set forth above, Applicants respectfully submit that the rejection based on the Pottenger et al.

reference is clear error. The specification, claims, knowledge of one skilled in the art, and Applicants'

remarks made herein and throughout prosecution, indicate that the claimed "system" comprising a "first

femoral component" and "second femoral component" are two separate femoral components.

claimed "first femoral component" and "second femoral component" cannot be different regions of the

same femoral component, as the Final Office Action asserts. The 12-27-05 Office Action even confirms

this fact by comparing the claimed "first femoral component" to a separate first femoral component 10f of

Colleran and the claimed "second femoral component" to a separate second femoral component 10a.

The cited art fails to disclose or suggest a "first femoral component" and a "second femoral

component" having different maximum medial to lateral dimensions, as set forth in independent Claims 1,

10, 18, and 24. Therefore, the Final Office Action fails to set forth a prima facie case under Section 102.

In light of this clear error and failure to set forth a prima facie rejection, Applicants respectfully request

that the Section 102 rejection based on Pottenger et al. be withdrawn.

Respectfully submitted,

Dated: Syst, 13, 2006

HARNESS, DICKEY & PIERCE, P.L.C.

P.O. Box 828

Bloomfield Hills, Michigan 48303

(248) 641-1600

5